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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/485,438	06/07/1995	STEPHEN EISENBERG	65850-1103.2	5619

22852 7590 10/15/2003

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
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1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/485,438

Applicant(s)

EISENBERG ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12 and 13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

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DETAILED ACTION*Status of Application*

Claims 12 and 13 are pending herein. A Judgment by the Board of Patent Appeals and Interferences in an Interference involving claims 12 and 13, Paper No. 26 mailed May 20, 2003, found that their subject matters were patentable to Applicant herein, the Senior Party in the Interference. Applicant's Request for a Corrected Filing Receipt, Paper No. 28 filed August 13, 1998, has been considered, and accordingly the spelling of the name of the co-inventor Robert P. Thompson was corrected and the name of David J. Dripps was deleted from the inventorship in accord with Paper No. 22 mailed June 18, 2001, wherein Applicant's Petition to Correct Inventorship, Paper No. 20 filed July 10, 1998, was acknowledged and granted. The continuing data portion of the filing receipt has also been corrected to indicate that the instant application is a Continuation-In-Part of the parent application serial No. 08/209,040 filed March 9, 1994, now Abandoned, which is a Continuation-In-Part of the grandparent application serial No. 07/943,369 filed September 9, 1992, and now Abandoned. The non-patent publications cited to the Board of Patent Appeals and Interferences by the parties to the Interference and supplied and made of record with Paper No. 27, Applicant's Information Disclosure Statement [IDs] filed August 24, 2003, as well as the six patents cited in Paper No. 27 and printed by the examiner have been reviewed and considered and are discussed below. While the instant application was involved in the Interference, two commonly-assigned applications sharing common inventors named herein were issued as U.S. Patents wherein certain claims conflict with either or both of claims 12 and 13 herein, necessitating the following rejections for obviousness-type double patenting.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to

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prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 10-18, and 23-25 of U.S. Patent No. 6,017,880. Although the conflicting claims are not identical, they are not patentably distinct from each other because methods of the patented claims 1-4 and 10-12 for *in vitro* inhibition of retrovirus infection of CD4⁺ cells by contacting compositions comprising the cells with a serine protease inhibitor [SLPI] protein embraces methods for inhibition of viral, and specifically retroviral, proliferation of claims 12 and 13 herein where inhibition of infection of cells by retroviruses of the patented claims will, according to the instant specification, necessarily result in an inhibition of viral, particularly retroviral, proliferation. Similarly, methods of the patented claims 13-18 and 23-25 for *in vivo* inhibition of retrovirus infection of CD4⁺ cells in a patient by treating the patient with a SLPI protein embraces methods for inhibition of viral, and specifically retroviral, proliferation of claims 12 and 13 herein where methods of inhibiting infection of cells by retroviruses in the patient of the patented claims will, according to the instant specification, necessarily result in an inhibition of viral, particularly retroviral, proliferation.

Claims 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,132,990. Although the conflicting claims are not identical, they are not patentably distinct from each other because a method of the patented claim 12 for treating a serine protease-mediated condition comprising administration of a serine protease inhibitor [SLPI]

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protein comprising a SLPI domain of the patented claim 1 embraces methods for inhibition of viral, and specifically retroviral, proliferation of claims 12 and 13 herein where administering a native SLPI in a method of the patented claim 12 comprising a SLPI domain of the patented claim 1 in order to treat a "serine protease-mediated condition" will necessarily include inhibition of viral, and specifically retroviral, proliferation of claims 12 and 13 herein because retroviral proliferation is, according to the instant specification, mediated by a serine protease inhibited by SLPI.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 13 are indefinite because neither claim recites a sequence identifier for the amino acid sequence of secretory leukocyte protease inhibitor [SLPI]. The claims fail to particularly point out and distinctly claim Applicant's intended subject matter because they do not indicate the positions for amino acid sequence alteration that could result in a generic SLPI in the context of any particular amino acid sequence. This rejection may be overcome by amending claims 12 and 13 to insert a further clause that states a particular sequence identifier, e.g., SEQ ID NO:3 herein.

Conclusion

The subject matter of claims 12 and 13 is free of the prior art and other publications made of record with Applicant's Information Disclosure Statement, Paper No. 27 filed 26 August 2003. The "Proposed List of Preliminary Motions" made of record with the IDS is not comprised of prior art publications and the article by McNeely et al. is not prior art as it was published a month after the instant application was filed. The article of Weber et

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al. discusses the substrate-binding site of the HIV-1 protease, characterized as an aspartic protease rather than a serine protease; while HIV-1 is a retrovirus, Weber et al. neither disclose nor suggest that a serine protease inhibitor, such as SLPI, might be used in methods of claims 12 and 13 herein. The article by Korant et al. discusses the use of two cysteine protease inhibitors, chicken cystatin and human cystatin C, for *in vitro* inhibition of poliovirus protease activity but neither discloses nor suggests that serine protease inhibitors, such as the SLPI, might be used in methods of claims 12 and 13 herein. The article by Ebina et al. discusses the use of a cysteine protease inhibitor, chicken cystatin, and a serine protease inhibitor, aprotinin, for *in vitro* inhibition of rotavirus protease activity but neither discloses nor suggests that the specific serine protease inhibitor SLPI might be used in methods of claims 12 and 13 herein. The patent to Glover et al. discusses methods of using synthetic serine protease inhibitors based on naturally occurring squash plant trypsin inhibitors to inhibit the activity of the serine proteases elastase, trypsin, and cathepsin G but neither disclose nor suggest that the specific serine protease inhibitor SLPI might be used in methods of claims 12 and 13 herein. The patent to Szabo discusses methods of using cysteine protease inhibitors, serine protease inhibitors, aspartic – termed carboxyl – protease inhibitors, and metalloprotease inhibitors to treat gastrointestinal ulcer disease but neither discloses nor suggests that the serine protease inhibitor SLPI might be used in methods of claims 12 and 13 herein. The patent to Kotwal et al. discusses the structures of two vaccinia virus gene products sharing discernable homology to “members of the serine protease inhibitor family”, but neither discloses nor suggests that the serine protease inhibitor SLPI might be used in methods of claims 12 and 13 herein. The ‘117 and ‘119 patents to Ledzey et al. disclose methods of treating, or of prophylaxis of, non-specific pulmonary and bowel inflammation, and mast cell-mediated skin inflammation, using the serine protease inhibitor α -1-antichymotrypsin but neither disclose nor suggest that the

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serine protease inhibitor SLPI might be used in methods of claims 12 and 13 herein. The disclosure of the use of several serine protease inhibitors, see claim 1 at col. 6, including SLPI for treating injuries or inflammatory diseases, including diseases of viral etiology, is not prior to the methods of claims 12 and 13 herein because the use of SLPI specifically for inhibition of viral, and retroviral, proliferation was first disclosed in the grandparent application serial No. 07/943,369, to which the instant application claims priority, which grandparent application was filed September 9, 1992, over six months before the filing date of the application issuing as the '762 patent to Ledzey et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
October 10, 2003

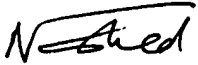

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER

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